Valvular heart disease
Original research

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Early clinical and haemodynamic matched comparison of balloon-expandable valves

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Abstract

Objectives The balloon-expandable Sapien-3 valve demonstrated superior results in terms of residual aortic regurgitation when compared with self-expandable devices. We aimed to compare for the first-time early outcomes of Sapien-3 transcatheter heart valve (THV) with the balloon-expandable Myval device.

Methods Consecutive real-world patients from nine European institutions with symptomatic severe aortic stenosis treated either with Sapien-3 or Myval THV devices after June 2018 were compared. Early clinical outcomes were prospectively gathered and blinded analysis of 30-day echocardiography was conducted. Matching for the following variables was performed: age, body surface area, Society of Thoracic Surgeons risk score, left ventricular function, mean gradient, transfemoral approach, aortic valvular calcium, aortic annulus mean diameter, area and eccentricity index.

Results A total of 416 patients treated either with the Sapien-3 (n=286, 68.7%) or with Myval THV (n=130, 31.3%) were included and 103 pairs compared after matching. Baseline characteristics were similar. Procedural success rate (Sapien-3: 94.2%; Myval: 93.2%, p=0.219), 30-day mortality (Sapien-3: 2.9%; Myval: 0.97%, p=0.625), clinical efficacy (12.6 vs 4.9%, p=0.057) and early safety (12.6 vs 4.9%, p=0.096) were comparable. There was a lower need for new permanent pacemaker (15.5 vs 5.8% p=0.020) with Myval. No significant differences were found in terms of ≥moderate aortic regurgitation (1% for Sapien-3, 0% for Myval, p=0.314), but mean gradients were higher following Sapien-3 than after Myval (p<0.001).

Conclusions The new Myval balloon-expandable THV was favourable in terms of safety, with low rate of permanent pacemaker and with favourable residual gradients and paravalvular leak rate according to blinded echocardiographic analysis.

Data availability statement

All data relevant to the study are included in the article or uploaded as supplementary information. All investigators have access to the database and the central pool of echocardiographic analysis. Due to research aims of monitoring all the information is available on request.

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Footnotes

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Contributors: JRDA and IJAS designed the project, collected and analysed the information and wrote the final manuscript. MXGM,

JH, FDM, CT, PM, FI, MA, PdH, FB, LNF, RM, SS, MM, CA-D, TR-D, GS, AB, IGS, SI, ARD and JASRC helped to collect data, performed critical review and approved the final version of the manuscript.

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